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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/692,145 | 10/22/2003 | James Kevin Carney | P1292 US | 9169 |
| 28390 | 7590 | 06/20/2006 | EXAMINER | |
| MEDTRONIC VASCULAR, INC. | | | ROY, ANURADHA | |
| IP LEGAL DEPARTMENT | | | ART UNIT | |
| 3576 UNOCAL PLACE | | | PAPER NUMBER | |
| SANTA ROSA, CA 95403 | | | 3736 | |

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/692,145 | Applicant(s) CARNEY ET AL. | |
| | Examiner Anuradha Roy | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/22/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a method of determining vulnerable plaque in a cardiovascular lumen, classified in class 600, subclass 481.
- II. Claims 18-22, drawn to a system for determining vulnerable plaque in a cardiovascular lumen, classified in class 600, subclass 549.
- III. Claims 24-25, drawn to an apparatus for determining vulnerable plaque in a cardiovascular lumen, classified in class 600, subclass 549.

The inventions are distinct because of the following reason:

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process, such as determining blockage within the brain.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination of a distance sensor has separate utility such as determining the length traveled within the vasculature. See MPEP § 806.05(d).

It is further noted, that the invention of Group I of this application contains claims directed to the following *four groups* of patentably distinct species:

- ❖ Group A: Species I, drawn to claim 2 & Species II, drawn to claim 3. The species are independent or distinct because they are directed to different embodiments of the guide member.
- ❖ Group B: Species III, drawn claim 4, Species IV, drawn to claim 5, & Species V, drawn to claims 6, 7, & 8. The species are independent or distinct because they are directed to different embodiments of the temperature sensor.
- ❖ Group C: Species VI, drawn to claim 9 and Species VII, drawn to claim 10. The species are independent or distinct because they are directed to different embodiments of the distance sensor.
- ❖ Group D: Species VIII, drawn to claim 15, Species IX, drawn to claim 16, & Species X, drawn to claim 17. The species are independent or distinct because they are directed different

embodiments of the method step of determining the vulnerable plaque and directed to the claims 15, 16, & 17.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Mr. Michael Jaro on May 24, 2006 a provisional election was made without traverse to prosecute the invention of Group II, claims 18-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-17 & 23-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18, 19, 21, & 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Diamantopoulos et al. (US Publication No. 2003/0120171).

Regarding claim 18, Diamantopoulos et al. discloses a system for determining vulnerable plaque in a cardiovascular lumen, comprising:

- ❖ means for inserting a guide member into the cardiovascular lumen (5), the guide member (17) including a temperature sensor (10) and a distance sensor [0032]-[0034];
- ❖ means for measuring a cardiovascular wall temperature with the temperature sensor (Abstract);

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- ❖ means for determining a distance from the temperature sensor to the cardiovascular wall with the distance sensor [0032]-[0034];
- ❖ means for adjusting the cardiovascular wall temperature measurement based on the distance determination [0047]-[0052];
- ❖ and means for determining the vulnerable plaque based on the adjusted cardiovascular wall temperature measurement ([0047]-[0052] & Abstract).

In regards to claim 19, Diamantopoulos et al. discloses a system further comprising:

- ❖ means for determining a baseline temperature of the cardiovascular lumen wall based on a plurality of adjusted cardiovascular wall temperature measurements [0011];
- ❖ means for comparing each adjusted cardiovascular wall temperature measurement to the baseline temperature [0011];
- ❖ and means for determining the vulnerable plaque when the adjusted cardiovascular wall temperature measurement is above the baseline temperature by at least a predetermined threshold [0011].

With regard to claim 21, Diamantopoulos et al. discloses a system further comprising: means for applying a therapy for the vulnerable plaque [0045].

With respect to claim 22, Diamantopoulos et al. discloses a system further comprising:

- ❖ means for determining a position of the vulnerable plaque (Abstract);
- ❖ and means for treating the vulnerable plaque [0045].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diamantopoulos et al. in view of Maahs et al. (US Publication No. 2003/0176810).

Regarding claim 20, Diamantopoulos et al. discloses a system for determining vulnerable plaque with all of the aforementioned elements. However, Diamantopoulos et al. does not disclose a means for measuring a fluid flow rate proximate the temperature sensor and the distance sensor with a flow sensor ([0043] & Abstract). However, Maahs et al. discloses a system having a means for measuring a fluid flow rate proximate the temperature sensor and the distance sensor with a flow sensor ([0043] & Abstract). It

would have been obvious to one having ordinary skill in the art at the time the invention in view of Maahs et al. to incorporate a flow sensor with Diamantopoulos et al. in order to measure the effects of the blood flow rate.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~


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